**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| WOMEN'S CHOICE PHARMACEUTICALS LLC,<br>850 Cassatt Road, Suite 210,<br>Berwyn, Pennsylvania 19312 | : | |
| *Plaintiff*, | : | Jury Trial Demanded |
| v. | : | |
| FIRST DATABANK, INC.<br>701 Gateway Blvd., Suite 600<br>South San Francisco, CA 94080 | : | |
| *Defendant*. | : | |

**COMPLAINT**

Plaintiff Women's Choice Pharmaceuticals LLC ("Plaintiff" or "WCP"), by and through its undersigned counsel, for its Complaint against First DataBank, Inc. ("Defendant" or "FDB"), hereby alleges and states the following:

**NATURE AND BASIS OF ACTION**

1. This action arises out of the false and misleading advertising and promotion of prescription prenatal vitamins in FDB's online drug database, which markets and advertises those prescription prenatal vitamins using a false and/or misleading classification. FDB's actions constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); and tortious interference with contract and prospective business relations in violation of Pennsylvania common law.

2. WCP seeks injunctive relief; actual and compensatory damages; punitive damages; recovery of WCP's costs and reasonable attorneys' fees incurred in connection with this action; and any other relief to which it is entitled and the interests of justice may require.

## THE PARTIES

3. Plaintiff WCP is a limited liability company organized under the laws of the State of Nevada, and is located and doing business at 850 Cassatt Road, Suite 210, Berwyn, Pennsylvania 19312.

4. Upon information and belief, Defendant FDB is a Missouri corporation with headquarters at 701 Gateway Blvd., Suite 600 South San Francisco, CA 94080. Upon information and belief, FDB is a subsidiary of Hearst Corporation, a multinational media and information services corporation that is headquartered at 300 W. 57th Street, New York, NY, 10019.

## JURISDICTION

5. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over WCP's state and common law claims pursuant to 28 U.S.C. § 1367.

6. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A substantial part of the events giving rise to the claims against FDB occurred in or through this District, and a substantial part of the harm is occurring and will occur in this District.

7. This Court has personal jurisdiction over FDB. Upon information and belief, FDB transacts business within this District, contracts to supply goods or services in this District, and/or owns, uses or possesses real property situated within the District. FDB's products and services, including its proprietary online drug database, are used by purchasers of the subject prenatal vitamins in this District and FDB has purposefully directed its business activities toward

this District. In addition, FDB's conduct has caused harm to WCP in this District. Through its conduct, FDB has purposefully availed itself of the privileges of conducting business in this District, and, when engaging in such conduct, it was reasonably foreseeable that FDB would be subjected to this Court's jurisdiction.

## WCP AND THE CRITICAL NEED FOR PRENATAL VITAMINS

8. WCP is a specialty pharmaceutical company that advertises, distributes, and sells high-quality pharmaceutical products throughout the United States, including prenatal vitamins.

9. WCP advertises and promotes its Nestabs line of prenatal vitamins through subscription Drug Databases such as FDB's Drug Database. WCP has imminent plans to launch an additional Nestabs prenatal vitamin, Nestabs One.

10. WCP maintains contractual and business relations with pharmaceutical manufacturers, wholesalers, distributors, and suppliers in order to make and sell its prenatal vitamins. These contractual and business relationships result in economic benefits to WCP, and will continue to do so in the future. These relationships are standard for the industry.

11. WCP maintains economic relationships with third party payers who pay for or assist in paying for WCP's prenatal vitamins prescribed to pregnant women and women of child bearing age.

12. Prescription ("Rx") prenatal vitamins, including WCP's Nestabs prenatal vitamins, typically contain 1–4 mg folic acid plus other vitamins and minerals and are vital for promoting healthy pregnancies.

13. Folic acid supplementation has been shown through extensive clinical investigations to be effective for decreasing the risks of neural tube defects (*i.e.*, defects in the development of the brain and spinal cord) during pregnancy. These benefits of folic acid have

been extensively documented in the FDA's rulemakings. See Exhibit 1, 61 Fed. Reg. 8752 (March 5, 1996).

14. The amount of evidence supporting folic acid use for this purpose has led a number of Federal agencies to recommend that women use prenatal vitamins containing folic acid to supplement their diet prior to conception and during the first trimester of pregnancy under the supervision and consultation of a physician or other health care professional.

15. FDA concluded in 1996 that: Based on the totality of the publicly available scientific evidence, there is significant scientific agreement among qualified experts that, among women of childbearing age in the general U.S. population, maintaining adequate folate intakes, particularly during the periconceptional interval, may reduce the risk of a neural tube birth defect-affected pregnancy. See Exhibit 1.

16. The National Academy of Sciences Institute of Medicine recommended in 1998 that women who could become pregnant should consume 400 µg synthetic folic acid/day from folate-fortified foods, supplements, or both. See Exhibit 2, CDC, "Folic Acid – Recommendations," available at http://www.cdc.gov/ncbddd/folicacid/recommendations.html. The American Academy of Pediatrics Committee on Genetics endorsed the U.S. Public Health Services' recommendation that all women who can become pregnant consume 400 µg folic acid/day to prevent neural tube defects. See Exhibit 3.

17. It is also well-accepted that pregnant women need other vitamins and minerals besides folic acid to support their own health and the health of their fetuses. See Exhibit 4. This is because during pregnancy, a woman's daily intake requirements for certain nutrients, other than folic acid – for example, calcium, iron, vitamin A, vitamin D, and vitamin B12 – will

increase. Id. These vitamins and minerals are all vital for proper fetal growth and development, as well as for the health of the mother.

18. The Federal Government has consistently recognized the need for prenatal vitamins that contain a variety of vitamins and minerals to ensure adequate prenatal health. FDA and HHS recommend that women of childbearing age who may become pregnant to not only consume adequate folic acid daily, but also iron and vitamin C. See Exhibit 5.

19. The American Pregnancy Association recommends that pregnant women avoid taking several different supplements, but instead take one multivitamin that includes a variety of required nutrients in one dose. Combining supplements (such as taking a folic acid supplement along with a multivitamin) can be unsafe because patients run the risk of overdosing on a particular nutrient.

20. Thus, providing one dosage unit (i.e., prenatal multivitamin) that contains both folic acid and vitamins/minerals significantly helps all women – particularly low-income women – with proper nutrient consumption, compliance, and payment.

## THE FDB DATABASE AND ITS CONSIDERABLE INFLUENCE OVER DRUG DISPENSING AND REIMBURSEMENT

21. Defendant FDB is a provider of subscription-based software and databases that provide clinical, regulatory, and pricing data about prescription drugs (collectively, the "FDB Database"). FDB is a critical gatekeeper of all information concerning pharmaceutical products in the United States and exercises considerable influence over the prescribing, dispensing, marketing, promotion, and reimbursement of pharmaceutical products in the United States.

22. The FDB Database is a specialized marketing channel that is used nationwide by manufacturers, wholesalers, distributors, pharmacies, pharmacists, insurers, health care professionals, third party payers, and others in the pharmaceutical industry.

23. FDB licenses the FDB Database to pharmacists, physicians, pharmacy benefit managers, insurers, wholesalers, distributors, payors and other pharmaceutical market participants around the nation involved in the business of prescribing, dispensing, marketing, promoting and paying for pharmaceutical products.

24. FDB represents that it provides "the most widely used and relied upon drug knowledge base in the United States and Canada" that "seamlessly integrates within healthcare information systems serving hospitals, long-term care facilities, physician practices, home health agencies, health plans, pharmacy benefit managers, retail pharmacies, web and mobile applications, and more."

25. According to FDB, the FDB Database is used for "electronic prescribing, pharmacy dispensing, drug claims processing, and drug pricing and competitive analysis" and enables "health care professionals to make more precise medication-related decisions to improve patient safety and healthcare outcomes."

26. FDB represents that it was rated the highest among "drug databases" in Influence on Decisions by the 2011 KLAS CDS report.

27. FDB's website advertises that subscribers should use its FDB Database due to its "Insights", claiming "We believe it's time to leverage the power of insightful thinking about drug knowledge to improve human health. All of which begins with a simple, but utterly complex, question: 'What if drug data was more than just data?'"

28. The FDB Database is used nationwide by manufacturers, wholesalers, distributors, pharmacies, pharmacists, insurers, health care professionals, and others in the pharmaceutical industry to make prescribing, purchasing, stocking, dispensing, marketing, and reimbursement decisions.

## FDB'S CHANGES TO THE CODING OF PRENATAL VITAMINS IN THE FDB DATABASE

29. In an announcement dated May 15, 2017, FDB notified subscribers of an update regarding its "Policy on Class Field and Prescription Designation on Dietary Supplements and Medical Foods." See Exhibit 7, FDB May 15, 2017 Notification. Specifically, FDB stated that, beginning June 2017, FDB will only apply a Class value of "F" to prescription drugs, bulk pharmaceutical ingredients, and prescription medical devices. Medical foods and dietary supplements, including prenatal vitamins, will no longer be allowed to be assigned a Class value of "F" in FDB's database (even if these products are sold only under a prescription).

30. Prescription dietary supplement products currently in the database with an "F" Class value will be reassigned the "O" Class value, "Products with no federal legal prescription requirement" by September 2017. At this time, WCP's Nestabs prenatal vitamins will be reassigned the "O" class value. Further, FDB has already begun assigning the "O" class value to prescription dietary supplements, including prenatal vitamins, which are newly listed in its database. Thus, WCP's Nestabs One prenatal vitamin will be assigned the "O" class value when launched.

31. Many industry participants in the pharmaceutical supply chain, as well as users of FDB's Database, believe the codes "F" and "O" to mean simply "prescription product" and "over-the-counter" product. As a result, FDB's decision to force a prescription product into an "O" field will give the false and misleading impression to the industry that these products are not to be dispensed by prescription for any reason, when in fact prenatal vitamins are commonly prescribed and dispensed under a prescription for health and safety reasons.

32. FDB's classification changes are false and misleading and will mislead the industry regarding the status of prescription prenatal vitamins. FDB's false and misleading

changes will frustrate the continued reimbursement and coverage of these vital products that will cause severe harm to the public health.

**FEDERAL AGENCY GUIDANCE CONCERNING PRENATAL VITAMINS**

33. The regulation of foods and prenatal nutrition for pregnant women originated in 1962 with the Foods for Special Dietary Uses rulemaking, which established that multivitamins for pregnant women were not a traditional "food" under the Federal Food, Drug, and Cosmetic Act ("FFDCA").

34. With the enactment of the Nutrition Labeling and Education Act of 1990 ("NLEA"), FDA further reviewed the relationship between folic acid and neural tube defects as relevant to food labeling. See Pub. Law No. 101-535 (November 8, 1990). The Agency determined that it would permit claims on both traditional foods and vitamins that folate could reduce the risk of neural tube defects.

35. FDA has recognized 1 mg as a demarcation between regulation as a dietary supplement and a prescription drug product. FDA has recognized the Department of Health and Human Service/Public Health Service recommendation that folate consumption of greater than 1 mg (1,000 µg)/day should be *under the supervision of a physician*. 58 Fed. Reg. 53,254, 53,256 (October 14, 1993).

36. Products containing prenatal vitamins and minerals, as well as 1 mg or more folic acid, are generally only sold by prescription or physician's order for use under the supervision of a physician.

37. FDA has approved NDAs and abbreviated new drug applications ("ANDAs") for folic acid products at levels 1 mg or greater, and has also approved applications for multi-nutrient products that contain folic acid for patients who are receiving parenteral nutrition. However, the Agency has never approved a single application for a prenatal prescription drug

that contained both folic acid as well as other active vitamins and minerals to support prenatal health.

38. The FDA recognizes that a product can be a prescription drug not only by reason of an approved application, but also when "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [the drug] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A).

39. Folic acid is essential to prenatal health, and multivitamins are essential to the health of both the mother and the fetus. The vast majority of prenatal multivitamins also contain folic acid to ensure that women, particularly low-income women, can receive a single doctor's prescription and obtain a single product without the expense associated with two separate products. To ensure that these products are continuously covered as mandated under Federal and State reimbursement programs, they must be listed with a prescription Class value in FDB's database.

40. Coverage of prenatal multivitamins by government health insurance programs, such as Medicaid, is vital to low-income families to ensure that they obtain the proper nutrition that is essential for families and helps prevent higher health care costs. Under these programs, the vitamins cannot be reimbursed unless they are dispensed by prescription.

## FDB'S DETRIMENTAL EFFECT ON COVERAGE UNDER CMS

41. The Medicaid program provides covered outpatient drugs ("CODs"), as defined in the Social Security Act ("SSA"), to qualifying individuals.

42. The SSA includes a list of several product classes that are specifically excluded from the definition of a COD, including prescription vitamin and mineral products. Critically,

prenatal vitamins are carved out of this class, meaning that prescription prenatal vitamins may not be excluded or otherwise restricted from coverage.

43. CMS confirmed coverage for prescription prenatal vitamins in a release to State Medicaid Directors in 2011, stating: "[a]s a reminder, prescription prenatal vitamins continue to meet the definition of a covered outpatient drug …." (emphasis in original).

44. CMS published its final rule in February 2016, reinforcing its historical approach of covering prescription prenatal vitamins, states that: … *states may not exclude or restrict coverage of prescription prenatal vitamins when prescribed for medically accepted indications.* (emphasis added).

45. Based upon these statutory provisions and CMS commentary, prescription prenatal vitamins cannot be restricted or excluded from Medicaid coverage merely because of their class (prenatal vitamins). Prescription prenatal vitamins are not required to have an approved NDA or ANDA. Nevertheless, these products are required to be dispensed by prescription in order to be eligible for reimbursement under Federal law.

**FDB WILL CAUSE CONFUSION CONCERNING STATE REIMBURSEMENT**

46. In addition to the problems that would arise under Federal law, FDB's change in policy will materially mislead state agencies into denying coverage of prescription prenatal vitamins.

47. There are many state laws under which states are required to cover prenatal vitamins as dietary supplements, but only if they are prescribed by a licensed provider. FDB's change in classification will cause confusion among states regarding the status of prescription prenatal vitamins and this confusion will cause these products to lose coverage.

48. Pennsylvania state law expressly provides for coverage for prescription prenatal vitamins. Pennsylvania code section § 1121.53 limits prenatal vitamin reimbursement for "Single entity and multiple vitamins *when prescribed* for prenatal use." (emphasis added).

49. A number of other states explicitly provide coverage of prescription prenatal vitamins as covered drugs, including Alabama, Alaska, Arkansas, California, Colorado, the District of Columbia, Idaho, Iowa, Kentucky, Maine, Mississippi, Missouri, New Hampshire, Ohio, Oklahoma, Rhode Island, Tennessee, Utah, Vermont, and Virginia. Thus, FDB's false and misleading classification of prenatal vitamins will cause denial of coverage in violation of Pennsylvania and other state law.

50. The prescription status of prenatal vitamins is of paramount importance for coverage and reimbursement. FDB's proposed re-categorization will have catastrophic effect on reimbursement of prenatal vitamins in some cases contrary to state laws, because it will mislead the industry into believing that these products are not prescription products when in fact they are prescription products for strong public health and safety reasons.

## FALSE ADVERTISING IN THE FDB DATABASE

51. FDB is aware that the listing of prenatal vitamins on the FDB database actually deceives or has the tendency to deceive a substantial segment of its audience into believing that prenatal vitamins are non-prescription and non-reimbursable products.

52. Through correspondence from the FDA to FDB dated June 29, 2017, FDB is aware that the FDA is concerned that FDB has misinterpreted the FDA's position and policies regarding medical foods, including prenatal vitamins, and mistakenly classified all medical foods products as over-the-counter (OTC) drugs although medical foods cannot simply be obtained from a retail establishment. FDB is aware that patients are losing or have lost insurance coverage for their products marketed as medical foods as a result of FDB's misclassification. Exhibit 8.

53. In a June 29, 2017 letter to FDB, the FDA stated that:

> FDA has been made aware of patients who are losing or *have lost insurance coverage* for their products marketed as medical foods. Stakeholders have contacted the agency, indicating that this is apparently the result of their insurance providers belief that the products are over-the-counter (OTC) drugs. We are concerned that this may be a result of First Databank's misinterpretation of FDA's position and policies on medical foods…We believe First Databank has misinterpreted FDA's response regarding the labeling of medical foods and mistakenly classified all medical foods products as over-the-counter (OTC) drugs…[A]lthough not required by the FD&C Act to be dispensed by prescription, the FD&C Act does not prohibit physicians from writing prescriptions for medical foods…As long as the labeling does not imply that the FD&C Act requires a prescription for the products, FDA does not object to manufacturers also indicated in the labeling of such products that prescriptions may be written for the product if doing so is consistent with applicable local, state, and federal laws…Medical foods are not OTC drugs and are not generally available at retail level. Again, although not required by federal law to be dispensed by prescription, physicians can and do write prescriptions for medical foods (as is frequently done for other products that do not require a prescription). Importantly, these products cannot simply be obtained from a retail establishment, but rather must be acquired through pharmacies, physicians, or directly from manufacturers based on evidence of a diagnosis of a disorder responsive to such a product."

54. Although this correspondence concerns medical foods, not prenatal vitamins specifically, the very same effect can be expected as FDB begins to implement its misclassification scheme for prenatal vitamins.

55. FDB is aware that drug formularies have relied or will rely on the FDB Database listing of prenatal vitamins to categorize prenatal vitamins as non-prescription for coverage purposes.

56. FDB is aware that altering the coding of prescription prenatal vitamins from prescription to actual or apparent over-the-counter status will result in reduced prenatal nutritional support.

57. Upon information and belief, FDB is aware that, as a result of its listing on the FDB database, prenatal vitamins have been or will be listed in pharmacy computer software as non prescription and/or non reimbursable.

58. FDB is aware that the listing of prenatal vitamins on the FDB database has been made available to WCP's customers in this District and that FDB's change in coding for prenatal vitamins adversely impacted WCP's sales of its prenatal vitamin products and WCP's goodwill and reputation in this District.

59. The advertising of the prenatal vitamins products on the FDB database has been transmitted to customers throughout the United States and in this judicial district.

60. WCP has suffered and will continue to suffer an immediate and substantial loss in market share as a direct result of the false and misleading advertising of prenatal vitamins, which is being disseminated and/or facilitated by FDB's advertising and promotion of the prenatal vitamins products on and through the FDB Database and FDB's services. WCP's launch of Nestabs One has been delayed by FDB's misclassification of newly listed prenatal vitamins to avoid industry confusion and adverse effects on reimbursement and sales.

61. Wholesalers and pharmacies will reduce inventories of all of WCP's prenatal vitamin products as a result of the false and misleading advertising of the prenatal vitamins products.

62. As a result, patients will be denied coverage for prenatal vitamins. This constitutes a threat to public health as many women will be unable or unwilling to pay for their prescriptions if they are not covered.

63. WCP has requested that FDB cease and desist disseminating and/or facilitating the dissemination of such false, inaccurate, misclassified, and misleading information.

64. FDB has nevertheless refused to cease and desist and persists in disseminating and/or facilitating the dissemination of false and misleading information regarding prenatal vitamins through the FDB database.

65. The ongoing promotion and advertising of the prenatal vitamins products as non-prescription products is false and misleading and will cause, and has caused irreparable injury to WCP and will continue to both damage WCP and to deceive and harm the public unless enjoined by this Court.

66. As a result of the ongoing advertising and promotion of prenatal vitamins through the FDB Database, payors, pharmacists, consumers and others in the industry have and will continue to be misled into believing that prenatal vitamins are not prescription products and are not reimbursable.

67. Upon information and belief, FDB is aware or should reasonably be aware of the contractual and business relationships that WCP maintains with pharmaceutical manufacturers, distributors and/or suppliers in order to make and sell prenatal vitamins, and the economic benefits to WCP that flow from these relationships.

68. Upon information and belief, FDB is aware of the economic relationship between WCP and third party payers of prescription prenatal vitamin products

69. WCP has already made substantial pre-launch investment in support of its imminent plans to launch an additional prenatal vitamin, Nestabs One. FDB's misclassification of WCP's prenatal vitamins will cause substantial and permanent economic harm to WCP for its entire line of Nestabs prenatal vitamins and has already caused economic harm to WCP by delaying WCP's launch of its new prenatal vitamin, Nestabs One.

70. Upon information and belief, FDB is aware that its June 2017 decision to only apply a Class value of "F" to prescription drugs, bulk pharmaceutical ingredients, and prescription medical devices will prevent the entry of new prenatal vitamin product formulations from entering the market because those products will not be reimbursed or covered under prescription drug plans.

## COUNT I

## FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT (15 U.S.C. § 1125(a)(1)(B))

71. WCP repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

72. Upon information and belief, FDB is advertising and promoting its databases and services as a unique marketing channel for prescription and non-prescription drugs.

73. Upon information and belief, FDB is advertising and promoting its databases and services as providing a competitive advantage for those in the prescription and non-prescription drug industry including marketers of drug information.

74. Upon information and belief, FDB is advertising and promoting its knowledge of drug data to potential and existing customers who can rely on FDB's knowledge to find accurate information concerning drug products and to make insurance reimbursement decisions.

75. Upon information and belief, FDB intends to misleadingly advertise and promote the prescription status of prenatal vitamins through the FDB database, automatic substitution algorithms, and/or data fields.

76. Upon information and belief, FDB is falsely and misleadingly advertising and promoting the prescription drug status of prenatal vitamins.

77. Such false and misleading statements about the prenatal vitamins have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of the prenatal vitamins.

78. Such false and misleading statements about the prenatal vitamins are material and likely to influence purchasing, dispensing, reimbursement, and stocking decisions of wholesalers, third-party payors, pharmacists, health care professionals and others in the pharmaceutical industry, as well as patients who consume WCP's products.

79. Such false and misleading statements about the prenatal vitamins are material and likely to influence patients access to WCP's products after a physician or other health care professional has prescribed a prenatal vitamin for the patient.

80. These false and misleading representations were and are made in interstate commerce.

81. As a direct and proximate result of FDB's conduct, WCP has suffered damages, which includes a loss of sales, profits and customers, which WCP would have made but for the false and deceptive representations by FDB.

82. Defendant's actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to WCP's business, reputation, and goodwill, unless FDB's unlawful conduct is enjoined by this Court.

83. Pursuant to 15 U.S.C. § 1116, WCP is entitled to preliminary and permanent injunctive relief to Defendant's continuing acts.

84. Pursuant to 15 U.S.C. § 1117, WCP is entitled to recover all damages sustained on account of FDB's actions, an accounting for profits realized by FDB, and the costs of this action.

85. FDB's actions have been willful and deliberate, entitling WCP to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), WCP is entitled to an award of reasonable attorneys' fees.

## COUNT II

## CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT (15 U.S.C. § 1125(a)(1)(B))

86. WCP repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

87. Additionally or alternatively, and upon information and belief, FDB is falsely and misleadingly representing that the prenatal vitamins are non-prescription and non-reimbursable through its listing of the product with the FDB database, and/or data fields.

88. Upon information and belief, FDB is knowingly inducing or causing, and/or materially participating in the false and misleading advertising and promotion of prenatal vitamins through the FDB Database and/or by other members of the pharmaceutical industry.

89. Upon information and belief, FDB knew and/or intended to participate in the false advertising of the prenatal vitamins on the FDB Database and by pharmacies, insurers, and/or other members of the pharmaceutical industry.

90. Upon information and belief, FDB actively and materially furthered such false and misleading advertising and promotion of prenatal vitamins as non-prescription and non-reimbursable.

91. Upon information and belief, FDB actively and materially furthered such false and misleading advertising and promotion of prenatal vitamins as non-prescription and non-reimbursable.

92. Such false and misleading statements about the prenatal vitamins on the FDB Database and by pharmacies, insurers and/or other members of the pharmaceutical industry have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of the prenatal vitamins.

93. Such false and misleading statements about the prenatal vitamins are material and likely to influence purchasing, dispensing, reimbursement, and stocking decisions of wholesalers, third-party payors, pharmacists, health care professionals and others in the pharmaceutical industry, as well as patients who consume WCP's products.

94. These false and misleading representations were and are made in interstate commerce.

95. As a direct and proximate result of FDB's conduct, WCP has suffered damages, which includes a loss of sales, profits and customers, which WCP would have made but for the false and deceptive representations by FDB.

96. FDB's actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to WCP's business, reputation, and goodwill, unless FDB's unlawful conduct is enjoined by this Court.

97. Pursuant to 15 U.S.C. § 1116, WCP is entitled to preliminary and permanent injunctive relief to Defendant's continuing acts.

98. Pursuant to 15 U.S.C. § 1117, WCP is entitled to recover all damages sustained by FDB's actions, an accounting for profits realized by FDB, and the costs of this action.

99. FDB's actions have been willful and deliberate, entitling WCP to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), WCP is entitled to an award of reasonable attorneys' fees.

## COUNT III

## TORTIOUS INTERFERENCE WITH CONTRACT OR BUSINESS RELATIONS AND EXPECTANCIES

100. WCP repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

101. FDB is aware of WCP's valid contractual and business relationships with manufacturers, distributors and/or suppliers that are maintained in order to make and sell prenatal vitamins.

102. FDB is aware of the economic benefits that flow to WCP as a result of these relationships, and the economic advantages, prospective and actual, deriving therefrom. FDB is further aware of the probability that economic benefits and advantages would continue to flow to WCP in the future as a result of these relationships.

103. FDB is aware that its wrongful and intentional conduct in making false and misleading representations to the pharmaceutical industry on a national scale, as set forth in this Complaint, constituting improper or illegal means, has interfered with WCP's valid contractual relationships.

104. Upon information and belief, FDB's wrongful and intentional conduct has caused third parties to discontinue or fail to enter into anticipated relationships with WCP, has caused a diminution in WCP's business expectancies or advantages deriving from its relationships, and/or caused injury to WCP's business relationships with third parties.

105. FDB's conduct has proximately caused damage to WCP in the form of lost sales, prescriptions and customers, and has thereby caused the diminution and erosion of the current and future economic benefits that flow from WCP's valid contractual and business relationships.

106. But for FDB's intentional and wrongful conduct, WCP would have realized the full economic benefits of its contractual and business relationships, anticipated contractual relationships and prospective economic advantages.

## JURY DEMAND

WCP demands a trial by jury of all issues so triable.

## PRAYER FOR RELIEF

WHEREFORE, WCP prays that the Court enter judgment in its favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial;

B. An award of punitive damages;

C. FDB's profits;

D. A preliminary and permanent injunction enjoining FDB from changing the "F" code designation for prenatal vitamins in any of FDB's databases, or otherwise representing that WCP's prenatal vitamins are non-prescription or non-reimbursable;

E. Enhanced damages, reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and as allowed under state law; and

F. Award WCP such other relief as the interests of justice may require.

DATE: August 18, 2017

Respectfully submitted,

**WOMEN'S CHOICE PHARMACEUTICALS LLC**

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